K013865

APR 2 2 2002

9 510(k) SUMMARY

Submitted By: Lisa Hopkins
Regulatory Affairs Coordinator
Cook Incorporated
750 Daniels Way
PO Box 489
Bloomington, IN 47402
(812) 339-2235

Device:
Trade Name: Tip Deflecting Endobronchial Blocker
Proposed Classification Name: Tracheal/Bronchial Differential Ventilation Tube

Predicate Devices or Legally Marketed Devices:
Bronchial Blocker Marketed & Distributed by Cook Incorporated
D.C. K962167

Pediatric Endobronchial Blocker Marketed & Distributed by Cook Incorporated
D.C. K002288

Device Description:
The Tip-Defecting Endobronchial Blocker is designed for use with a standard endotracheal tube and a small diameter fiberoptic bronchoscope to be placed inside a single lumen tube to provide one-lung ventilation. It uses a flexible soft tip that can be deflected to more than 90 degrees and easily placed into the desired bronchus to be blocked. The device measures 9.0 French in outside diameter and fits coaxially with a 7.0 mm or larger endotracheal tube. The proximal end of the catheter is made up of a Y-fitting. One port of the Y-fitting is connected to a pilot balloon assembly. This balloon assembly facilitates inflation of the distal balloon and maintains inflation until it is released. Components of this device will include an Arndt Multiport Airway Adapter (Class I, Exempt, §868.5810), a CPAP Adapter (Class I, Exempt, §868.5810), and a syringe (vendor supplied).

Indications for Use:
The Tip Deflecting Endobronchial Blocker is intended for use to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures which require one-lung ventilation.

Substantial Equivalence:
The Tip Deflecting Endobronchial Blocker is similar to the Cook Bronchial Blocker, D.C. # K962167 and the Pediatric Endobronchial Blocker, D.C. #K002288. The similar indications for use and technological characteristics of the Tip Deflecting Endobronchial

Blocker as compared to the predicate devices support a determination of substantial equivalency.

Test Data:
The Tip Deflecting Endobronchial Blocker was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Analysis of Bond Strength
- Analysis of Deflection Angles
- Analysis of Cuff Pressure and Dimension at Various Inflation Volumes
- Balloon Burst Testing
- Analysis of Balloon Cuff Inflation Retention
- Evaluation of Balloon to Shaft Bond
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a Bronchial Differential Ventilation Tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2002

April Lavender, RAC
Vice President, Regulatory Affairs
Cook Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402-0489

Re: K013865
Trade/Device Name: Tip Deflecting Endobronchial Blocker
Regulation Number: 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: 73 CBI
Dated: April 9, 2002
Received: April 15, 2002

Dear Ms. Lavender:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tip Deflecting Endobronchial Blocker
Special 510(k) Premarket Notification
Cook Incorporated

510(k) Number (if known): K013865

Device Name: Tip Deflecting Endobronchial Blocker

Indications for Use:

The Tip Deflecting Endobronchial Blocker is intended for use to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures which require one-lung ventilation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013865